



Original Contribution

Detection of acute myocardial ischemic injury by gender using a novel cardiac electrical biomarker^{☆,☆☆,★}

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ABSTRACT

Objective: The objective of this study was to stratify by gender a new cardiac electrical biomarker (CEB) diagnostic accuracy for detection of acute myocardial ischemic injury (AMII).

Methods: This is a noninferiority retrospective, case-control, blinded study of 310 archived measured electrocardiograms (ECGs) acquired from 218 men and 92 women. The CEB is constructed from the derived ECG (dECG) synthesized from 3 leads. Electrocardiograms were included if acquired less than or equal to 1 day from patient presentation. Electrocardiograms were interpreted by 2 blinded physicians and adjudicated by consensus. Standard ST analyses and computerized ECG interpretations were active controls. Electrocardiograms were excluded for noise and baseline wander, age younger than 18 years, and ectopic beats in the 10-second ECG acquisition. Diagnostic accuracy measures of sensitivity, specificity, positive and negative predictive values, and likelihood ratios were stratified by gender. Measured vs derived ECG correlations were quantitatively compared using Pearson correlation and qualitatively by percent agreement methodology.

Results: The CEB sensitivities for AMII detection in men and women were 93.9% and 90.5%, respectively, and CEB specificities were 90.7% and 95.2%, respectively, and were superior to active controls. Derived and measured ECGs showed high correlation for both men and women with $r = 0.857$ and $r = 0.893$, respectively. Reference standard intra-agreement analysis for measured ECGs and dECGs with AMII was 99.4%.

Conclusions: The CEB demonstrates high diagnostic accuracy for detection of AMII in men and women. The ECG can be derived with accuracy from 3 leads. This technology is an efficient real-time method of identifying patients with AMII who are being monitored in acute care settings.

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1. Introduction

The concepts of a new and novel cardiac electrical biomarker (CEB) and the derived 15-lead electrocardiogram (ECG) have been recently reported by Schreck and Fishberg [1,2]. Briefly, cardiac electrical activity is reported to be highly dipolar [3,4], and as such, only 3 measured orthogonal leads should be needed to actually derive this composite 15-lead ECG from just 5 body surface electrodes that are connected to a cardiac rhythm monitoring device. This will allow continuous cardiac

rhythm monitoring with the added simultaneous advantage of acquiring the derived 12-lead ECG (dECG) and scalar 3-lead derived vectorcardiogram, a composite 15-lead ECG, instantaneously and in real-time using 1 cardiac rhythm monitoring device. The objective of this study is to identify the CEB diagnostic accuracy, stratified by gender, compared to active controls (ACs).

2. Materials and methods

This is a noninferiority, retrospective, blinded, case-control, paired comparator [5] study of ECGs from 218 men and 92 women. These 310 measured ECGs (mECGs) of various morphologies were obtained from 2 databases including an archived National Institutes of Health-funded Physiobank PTBDB database [6] and a database from Muhlenberg Regional Medical Center (Plainfield, NJ). The Muhlenberg Regional Medical Center database includes consecutive patients who were admitted to the emergency department (ED) with chest pain. Patients included men and women, age 18 years or older. The standard mECGs were acquired using a Marquette MAC-15 machine (GE Healthcare, Waukesha, WI). The study ECGs represent a gender stratification subanalysis of a recent prior study by Schreck and Fishberg [1].

[☆] Prior presentations: Concepts in this manuscript have been presented at a prior meeting: Schreck DM, Fishberg RD. Detection of acute myocardial ischemic injury by gender using a novel cardiac electrical biomarker. Presented at the American College of Emergency Physicians Research Forum. Chicago, IL, October 28, 2014.

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[★] Dr David M. Schreck owns a significant nonmajority interest in VectraCor that constitutes greater than 5% of the entity. VectraCor is the medical device company that manufactures the device used in this study.

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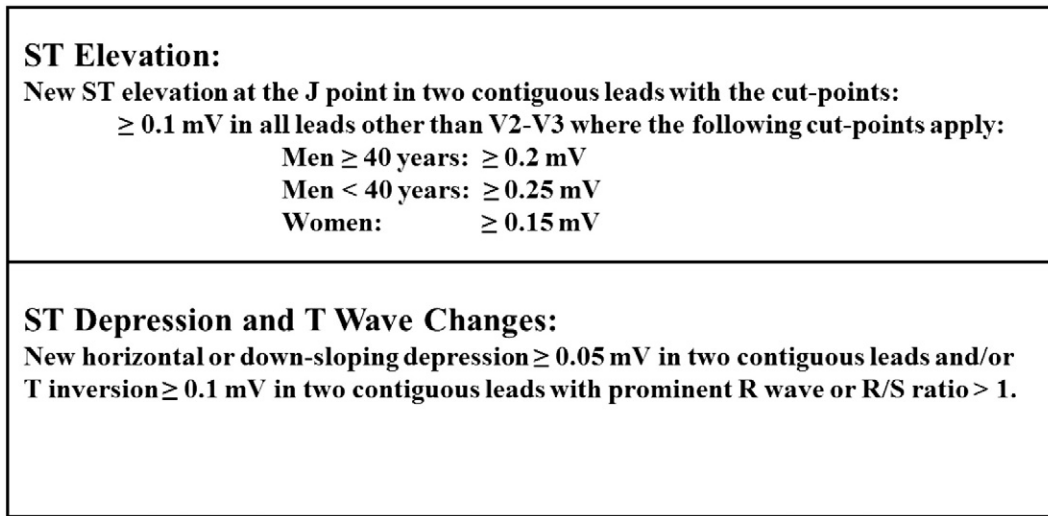
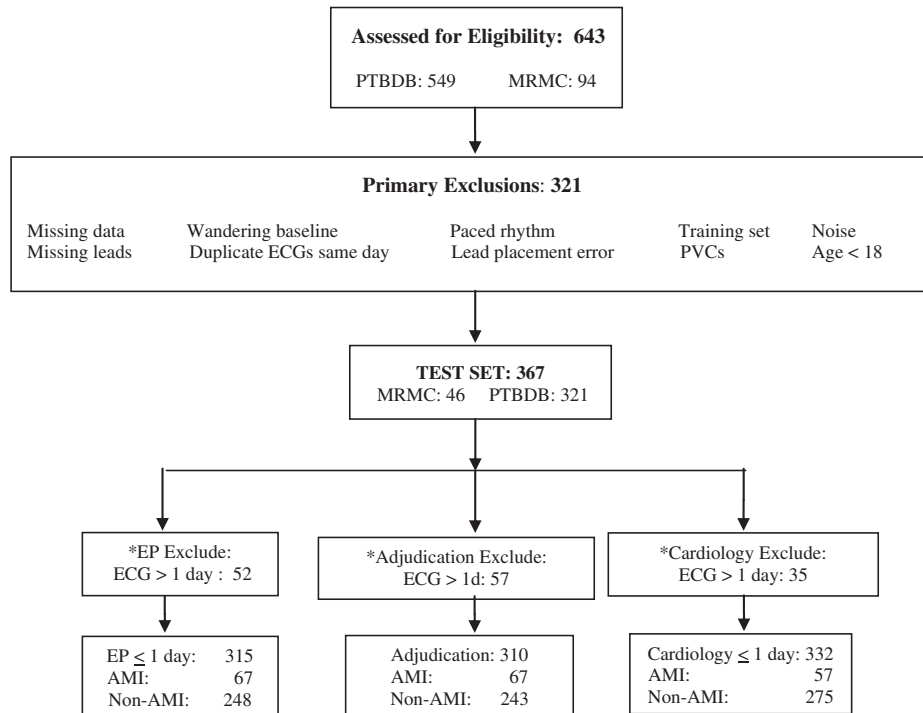


Fig. 1. ST criteria for ECG interpretation of AMI.

Electrocardiograms were included if acquired less than or equal to 1 day from patient presentation. Electrocardiograms were excluded for excessive noise and baseline wander, age younger than 18 years, and paced or ectopic beats in the 10-second ECG period from which a “median beat” is determined.

The dECGs were constructed from 3 measured leads I, II, and V₂, which were converted to a 3-lead orthogonal basis set of {I, aVF, V₂} [7] using Einthoven triangular geometric relationships. The 15-lead dECGs were synthesized from this orthogonal lead set. The CEB is constructed from the median beat from each dECG using the VectraplexECG



*Note: Differences between EP, Adjudication and Cardiology sample size is due to diagnosis and associated exclusion criteria

- ECG = Electrocardiogram
- UPTM = Universal patient transformation matrix
- PVC = Premature ventricular contraction
- EP = Emergency physician
- AMI = Acute myocardial infarction

Fig. 2. Flow diagram for case enrollment. Abbreviations: UPTM, universal patient transformation matrix; PVC, premature ventricular contraction; AMI, acute myocardial infarction.

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